

**Amendment and Response**

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Serial No.: 09/738,599

Confirmation No.: 1240

Filed: 15 December 2000

For: NUCLEIC ACID ENCODING AN AVIAN *E. COLI* ISS POLYPEPTIDE AND METHODS OF USE**Amendments to the Claims**

This listing of claims replaces all prior versions, and listings, of claims in the above-identified application:

1-29. (Canceled)

30. (Currently Amended) An isolated nucleic acid molecule comprising nucleotides 73 to 309 of the nucleotide sequence of SEQ ID NO:22.

31. (Currently Amended) The isolated nucleic acid molecule of claim 30 further comprising nucleotides 1 to 33 of the nucleotide sequence of SEQ ID NO:21, wherein the 33 nucleotides of the nucleotide sequence of SEQ ID NO:21 are located 5' of the nucleotides 73 to 309 of the nucleotide sequence of SEQ ID NO:22.

32. (Currently Amended) The isolated nucleic acid molecule of claim 30 wherein the nucleotides 73 to 309 of the nucleotide sequence of SEQ ID NO:22 are operably linked to a promoter functional in a host cell so as to form an expression vector.

33. (Currently Amended) An expression vector comprising an isolated nucleic acid molecule comprising nucleotides 73 to 309 of the nucleotide sequence of SEQ ID NO:22, operably linked to at least one regulatory sequence or control sequence.

34. (Canceled)

35. (Withdrawn) A method of using a nucleic acid molecule encoding an *E. coli* Iss polypeptide, the method comprising:

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providing a host cell stably transformed with an expression vector comprising a nucleic acid molecule of claim 30, operably linked to a least one regulatory sequence or control sequence recognized by the host cell; and

expressing the nucleic acid molecule to yield an *E. coli* Iss polypeptide.

36. (Withdrawn) The method of claim 35 wherein the nucleic acid molecule further comprises nucleotides 1 to 33 of the nucleotide sequence SEQ ID NO:21 located 5' of nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22.

37. (Currently Amended) An immunogenic composition comprising:  
an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an avian *E. coli* Iss polypeptide or an immunogenic fragment or immunogenic subunit of the avian *E. coli* Iss polypeptide, wherein the nucleic acid molecule further comprises at least one regulatory sequence or control sequence operably linked to the nucleotide sequence encoding the polypeptide; and  
a pharmaceutically acceptable carrier.

38. (Previously Presented) The immunogenic composition of claim 37 wherein the nucleic acid molecule is included in a vector.

39. (Original) The immunogenic composition of claim 38 wherein the vector is a plasmid.

40. (Original) The immunogenic composition of claim 38 wherein the vector is a viral vector.

41. (Previously Presented) The immunogenic composition of claim 37 wherein the at least one regulatory sequence or control sequence causes expression of the polypeptide in an animal cell.

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42. (Previously Presented) The immunogenic composition of claim 38 wherein the nucleic acid molecule further comprises an immunostimulatory nucleotide sequence.
43. (Cancelled)
44. (Currently Amended) The immunogenic composition of claim 38 wherein the nucleic acid molecule comprises nucleotides 73 to 309 of the nucleotide sequence of SEQ ID NO:22.
45. (Currently Amended) The immunogenic composition of claim 44 wherein the nucleic acid molecule further comprises nucleotides 1 to 33 of the nucleotide sequence of SEQ ID NO:21 located 5' of the nucleotides 73 to 309 of the nucleotide sequence of SEQ ID NO:22.
46. (Withdrawn) A method for using an immunogenic composition comprising:  
providing the immunogenic composition of claim 37; and  
administering the immunogenic composition to a subject diagnosed with, at risk of, or exhibiting symptoms of an *E. coli* infection.
47. (Withdrawn) The method of claim 46 wherein the *E. coli* infection is selected from the group consisting of septicemic disease, colibacillosis, coligranuloma, peritonitis, salpingitis, synovitis, and omphalitis.
48. (Withdrawn) The method of claim 46 wherein the nucleic acid molecule is included in a vector.
49. (Withdrawn) The method of claim 48 wherein the vector is a plasmid.
50. (Withdrawn) The method of claim 48 wherein the vector is a viral vector.

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51. (Withdrawn) The method of claim 46 wherein the nucleic acid molecule further comprises at least one regulatory sequence or control sequence operably linked to the nucleotide sequence encoding the polypeptide.
52. (Withdrawn) The method of claim 46 wherein the nucleic acid molecule further comprises an immunostimulatory sequence.
53. (Withdrawn) The method of claim 46 wherein the nucleic acid molecule comprises nucleotides 73 to 309 of SEQ ID NO:22 or a subunit or fragment thereof.
54. (Withdrawn) The method of claim 53 wherein the nucleic acid molecule comprises nucleotides 73 to 309 of SEQ ID NO:22.
55. (Withdrawn) The method of claim 53, the nucleic acid molecule further comprising nucleotides 1 to 33 of SEQ ID NO:21 located 5' of nucleotides 73 to 309 of SEQ ID NO:22.
56. (Withdrawn) The method of claim 46 wherein the subject is selected from the group consisting of a bird, a cow and a mink.
57. (Withdrawn) A method for making an immunogenic composition, the method comprising combining a pharmaceutically acceptable carrier and the isolated nucleic acid molecule of claim 30.
58. (Withdrawn) A method for vaccinating a subject comprising administering to the subject the composition of claim 37 in an amount effective to result in an immune response that is specific for the Iss polypeptide.

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59. (Withdrawn) The method of claim 58 wherein the nucleic acid molecule is included in a vector.

60. (Withdrawn) The method of claim 58 wherein the nucleic acid molecule further comprises a regulatory sequence or a control sequence operably linked to the nucleotide sequence encoding the polypeptide.

61. (Withdrawn) The method of claim 58 wherein the nucleic acid molecule further comprises an immunostimulatory nucleotide sequence.

62. (Withdrawn) The method of claim 58 wherein the subject is selected from the group consisting of a bird, a cow or a mink.

63. (Withdrawn) A method for treating or preventing disease in a subject caused by a complement resistant *E. coli* comprising administering to the subject a vaccine comprising the isolated nucleic acid molecule of claim 30.

64. (Withdrawn) The method of claim 63 wherein the nucleic acid molecule comprises a vector.

65. (Withdrawn) The method of claim 63 wherein the nucleic acid molecule further comprises a regulatory sequence or a control sequence operably linked to the nucleotide sequence encoding the polypeptide.

66. (Withdrawn) The method of claim 65 wherein the nucleic acid molecule further comprises an immunostimulatory sequence.

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67. (Currently Amended) The immunogenic composition of claim 44 wherein the immunogenic composition generates an antibody response against the polypeptide, ~~subunit, or fragment~~ when administered to a subject.
68. (Currently Amended) An immunogenic composition comprising:  
an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an avian *E. coli* Iss polypeptide or an immunogenic fragment or immunogenic subunit of the avian *E. coli* Iss polypeptide, wherein the nucleic acid molecule is operably linked to a promoter and further comprises an immunostimulatory nucleotide sequence;  
and  
a pharmaceutically acceptable carrier.
69. (Currently Amended) An immunogenic composition comprising:  
an isolated nucleic acid molecule comprising a nucleotide sequence comprising nucleotides 73 to 309 of the nucleotide sequence of SEQ ID NO:22 and a promoter operably linked to the nucleic acid molecule; and  
a pharmaceutically acceptable carrier.
70. (Currently Amended) An immunogenic composition comprising:  
an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an avian *E. coli* Iss polypeptide or an immunogenic fragment or immunogenic subunit thereof, wherein the nucleic acid molecule comprises nucleotides 73 to 309 of the nucleotide sequence of SEQ ID NO:22, ~~wherein the nucleic acid molecule further comprises nucleotides 1 to 33 of the nucleotide sequence of SEQ ID NO:21 located 5' of~~ nucleotides 73 to 309 of the nucleotide sequence of SEQ ID NO:22, and a promoter operably linked to the nucleic acid molecule; and  
a pharmaceutically acceptable carrier.

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71. (New) The immunogenic composition of claim 69, wherein the promoter is a eukaryotic promoter and the polypeptide comprising an avian *E. coli* Iss polypeptide or an immunogenic fragment or immunogenic subunit thereof is expressed in an animal cell.
72. (New) The immunogenic composition of claim 69, wherein the promoter is a eukaryotic promoter and the nucleic acid molecule forms an expression vector suitable for use in an animal cell.
73. (New) The immunogenic composition of claim 70, wherein the promoter is a eukaryotic promoter and the polypeptide comprising an avian *E. coli* Iss polypeptide or an immunogenic fragment or immunogenic subunit thereof is expressed in an animal cell.